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| APPLICATION NO.     | FILING DATE                           | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|---------------------|---------------------------------------|-----------------------|-------------------------|------------------|--|
| 09/896,324          | 06/29/2001                            | Bi-Yu Li              | TM0011-UT 8386          |                  |  |
| 27740               | 9590 03/24/2003<br>ESA RESEARCH INSTI | TUTE                  | EXAMINER                |                  |  |
|                     | JAL PROPERTY DEPART                   | CHUNDURU, SURYAPRABHA |                         |                  |  |
| SAN DIEGO, CA 92121 |                                       |                       | ART UNIT                | PAPER NUMBER     |  |
|                     |                                       |                       | 1637                    |                  |  |
|                     |                                       |                       | DATE MAILED: 03/24/2003 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |  | Application | No.   | Applicant(s)  |  |  |  |  |
|--|--|-------------|---|---|--|--|--|--|
|  |  | 09/896,324  |   | LI ET AL.   |  |  |  |  |
|  | Office Action Summary  | Examiner    |   | Art Unit  |  |  |  |  |
|  |  | Suryaprabha |   | 1637  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address  |  |             |   |   |  |  |  |  |
| Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |             |   |   |  |  |  |  |
| Status   |  |             |   |   |  |  |  |  |
| 1)区  |  |             |   |   |  |  |  |  |
| 2a) <u></u> ☐  | This action is <b>FINAL</b> . 2b) This action is non-final.  |             |   |   |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |  |             |   |   |  |  |  |  |
| Disposition of Claims  |  |             |   |   |  |  |  |  |
| 4) Claim(s) 1-23 is/are pending in the application.  |  |             |   |   |  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |             |   |   |  |  |  |  |
| 5)   | 5) Claim(s) is/are allowed.  |             |   |   |  |  |  |  |
| 6)   | 6) Claim(s) is/are rejected.   |             |   |   |  |  |  |  |
| , ·—   | Claim(s) is/are objected to.   |             |   |   |  |  |  |  |
| 8) Claim(s) <u>1-23</u> are subject to restriction and/or election requirement.  |  |             |   |   |  |  |  |  |
| 1  | on Papers  | or          |   |   |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |  |             |   |   |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |             |   |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be field in abbyance. See an extraction filed on is: a) approved b) disapproved by the Examiner.  |  |             |   |   |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.   |  |             |   |   |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.  |  |             |   |   |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |  |             |   |   |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |  |             |   |   |  |  |  |  |
| 1  | a) ☐ All b) ☐ Some * c) ☐ None of:   |             |   |   |  |  |  |  |
|  | 1. Certified copies of the priority documents have been received.  |             |   |   |  |  |  |  |
|  | 2. Certified copies of the priority documents have been received in Application No   |             |   |   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.   |  |             |   |   |  |  |  |  |
| 14)  | 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).                               |             |   |   |  |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |  |             |   |   |  |  |  |  |
| Attachment(s)  |  |             |   |   |  |  |  |  |
| 2) Noti  | ce of References Cited (PTO-892)<br>ce of Draftsperson's Patent Drawing Review (PTO-948)<br>rmation Disclosure Statement(s) (PTO-1449) Paper No(s) | )           | 4) Interview Summa 5) Notice of Informa 6) Other: | ary (PTO-413) Paper No(s)  I Patent Application (PTO-152) |  |  |  |  |

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## **DETAILED ACTION**

## Restriction/election

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-13 and 16-21, drawn to a method for amplification and production and detection of a population of polynucleotides, classified in class 435, subclass 6, and 91.2.
- II. Claim(s) 22, drawn to a method for diagnosing a disease, condition, or disorder, classified in class 514, subclass 44.
- III. Claim(s) 14, drawn to a recombinant host cell transformed with a vector, classified in class 435, subclass 252.3.
- IV. Claim(s) 23, drawn to an isolated nucleic acid, requiring SEQ ID Nos. 2-65, classified in class 536, subclass 24.33.
- 2. The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product in Group III can be used in a materially different processes such as gene therapy or hybridization assays.

Inventions in Group III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the product in Group III can be used in a materially different processes such as gene therapy or hybridization assays.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions in Group III and IV have different modes of operation, different functions and different results. For instance, the inventions in Group III and IV can be used independently from each other thus each product of Groups III and IV has different mode of operation with different function and effect.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions in Group I and II have different modes of operation, different functions and different results. For instance, the invention in Group II is used to diagnose an individual with an end result of diagnosing a disease or disorder. It has different mode of operation with different function and effect.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the search for one group is not required for any other group, restriction for examination purposes as indicated is proper.

In this application additionally, if applicant elects Group IV, applicant is required to specify *one* specific nucleotide sequence for examination. This requirement is made under 1192 O.G. 68

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Notice (November 19, 1996 and revised MPEP), as the examination of more than one sequence in the application would result in an undue search burden on the PTO.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Bezion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryapabha Chunduru

March 19, 2003

JEFFREY FREDMAN